Remarks/Arguments:

This amendment does not add or cancel any claims, and is provided to amend claims 1-3. However, in doing so, no new matter has been added, and no claims have been narrowed. Upon entry of this amendment, claims 1-6 will be pending, wherein claims 1-3 are independent.

In the present amendment, the Applicants have made non-narrowing amendments to independent claims 1, 2 and 3. However, the previous arguments in the response and amendment filed on January 19, 2010 are still applicable, and are repeated below.

Objections to the Drawing

The Examiner is thanked for the withdrawal of the objections to the drawings.

Objection to the Specification

The Examiner is also thanked for the withdrawal of the objection to the specification.

Rejections of the Claims under 35 U.S.C. 102

The Examiner has previously rejected claims 2 and 5 under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 6,186,982 of Gross et al. (hereinafter Gross 1).

Specifically, the Examiner pointed to Gross 1 as disclosing a device for delivering a medicament having a housing with a top, a bottom surface adapted to contact a skin surface of a patient, a needle aperture on the bottom surface, and an injection needle adapted for penetration of the skin surface and for movement through the needle aperture.

The Examiner also pointed to Gross 1 as disclosing such a device further having a reservoir disposed within the housing in fluid communication with the injection needle, and a safety member adapted for movement substantially perpendicular to the bottom surface of the housing, having a skin contacting portion disposed about the needle aperture and substantially covered with adhesive, and at least one shield protruding from the skin contacting portion, the safety member having a first position wherein the shield of the safety member is initially disposed within the housing and the skin contacting portion is

substantially co-planar with the bottom surface of the housing, and a second position wherein the shield of the safety member is at least partially withdrawn from the housing and at least partially covers the injection needle.

The Examiner also pointed to Gross 1 as disclosing such a safety member wherein when the device is placed upon the skin surface of the patient, the skin contacting portion of the safety member is temporarily adhered to the skin surface and when the device is removed from the skin surface, the adhesion of the safety member to the skin surface is sufficient to move the safety member from the first position to the second position, such that the Gross 1 reference purportedly anticipates the device as recited by the Applicants in claims 2 and 5.

As noted above, in the present amendment, the Applicants have made non-narrowing amendments to independent claims 1, 2 and 3. However, the previous arguments in the response and amendment filed on January 19, 2010 are still applicable, and are repeated below.

In regard to independent claim 2, the Applicants recite an adhesive/skin surface activation feature wherein the adhesion (of the skin contacting portion of the safety member) to the skin surface is sufficient to activate the *linear movement* of the safety member. That is, in an exemplary embodiment of the present invention the safety member is linearly moved substantially *perpendicular to the bottom surface* of the device upon removal.

In contrast, the Gross 1 reference describes a subcutaneous drug delivery device wherein a displaceable cover 52, provided with an adhesive, *rotates* about a hinge to and from a lower surface of the device 53 to cover a needle 51 (see col. 11, lines 34-50). That is, the Gross 1 reference describes a system and method wherein the displaceable cover is rotated to cover the needle, but does not describe a linear movement substantially perpendicular to the bottom surface of the device upon removal as recited by the Applicants. Even in the case of the locking mechanism 64, the cover elements of the Gross 1 reference are rotatable to provide any extensions thereof, and do not linearly extend substantially perpendicular to the bottom surface.

The Applicants further recite the shield being configured to be held in place by a device activation button, such that the safety member has a first position wherein the shield

is initially disposed within the housing and held in place by the device activation button, and a second position wherein the shield of the safety member is released by activation of the device activation button and is at least partially withdrawn from the housing substantially perpendicular to the bottom surface, preferably through the adhesion force of the adhesive of the skin contacting portion.

Accordingly, for at least these reasons, the Applicants assert that the Gross 1 reference does not disclose or reasonably suggest each element as recited in claims 2 and 5, and respectfully request the withdrawal of the rejection under 35 U.S.C. 102(b).

The Examiner has also previously rejected claims 3 and 6 under 35 U.S.C. 102(e) as being anticipated by Gross 1.

Specifically, the Examiner pointed to Gross 1 as disclosing a device for delivering a medicament having a housing with a top, a bottom surface adapted to contact a skin surface of a patient, a needle aperture on the bottom surface, and an injection needle adapted for penetration of the skin surface and for movement through the needle aperture.

The Examiner also pointed to Gross 1 as disclosing such a device further having a reservoir disposed within the housing in fluid communication with the injection needle, and a safety member adapted for rotational movement along an arcuate path relative to the bottom surface of the housing, and having a skin contacting portion disposed about the needle aperture and substantially covered with adhesive, and a pivot, such that the safety member has a first position wherein the safety member is substantially co-planar with the bottom surface of the housing, and a second position wherein the safety member is rotated about the pivot and the safety member at least partially covers the injection needle.

The Examiner also pointed to Gross 1 as disclosing such a safety member wherein when the device is placed upon the skin surface of the patient, the skin contacting portion of the safety member is temporarily adhered to the skin surface and when the device is removed from the skin surface, the adhesion of the safety member to the skin surface is sufficient to rotate the safety member about the pivot from the first position to the second position, such

that the Gross 1 reference purportedly anticipates the device as recited by the Applicants in claims 3 and 6.

In regard to independent claim 3, the Applicants recite the safety member as having *a securing means* while in the first position such that the safety member is *secured* against and substantially co-planar with the bottom surface of the housing in the first position, such as in a pre-use position. This can be achieved through the use of, for example, the door 790 and door latch 791 of Fig. 39 (see also paragraph 319), and the lock arm 1034 of Fig. 123 (see also paragraph 342). For example, the device can be positioned against a skin surface, and movement of the push button releases the latch or lock arm. However, as the device is adhesively positioned against a user's skin, no movement of the safety member is allowed, but is free to move upon removal of the device. In doing so, the Applicants recite a system and method wherein the safety member has a securing means while in the first position such that the safety member is secured against and substantially co-planar with the bottom surface of the housing, such as in a pre-use position.

In contrast, the Gross 1 reference describes a subcutaneous drug delivery device wherein the displaceable cover 52, provided with an adhesive, can rotate about a hinge 54 from a lower surface of the device 53 to cover a needle 51 (see col. 11, lines 34-50). However, the Gross 1 reference describes the system and method wherein the displaceable cover is extended in a normal state (i.e., rotated from the bottom surface) to cover the needle both prior to and after use. That is, only an application of the device to a skin surface will serve to rotate the cover 52 toward and against the bottom surface of the device as shown in Fig. 5. At all other times, the absence of the skin surface allows the cover 52 to assume the shielding position as shown in Figs. 4 and 6. Accordingly, the Applicants assert that none of Figs. 4-6 of Gross 1 show the cover 52 *secured* against the bottom surface as recited by the Applicants.

For example, in a pre-use position, the cover 52 is extended and is prevented from movement toward a lower surface of the device by tab 55 (see for example, Fig. 4). Specifically, the tab 55 is provided to prevent the cover 52 from rotating toward the lower surface of the device 53 until removed at use. During use, contact with the skin surface

rotates the cover 52 toward and against the bottom surface of the device (see for example, Fig. 5), but there is no provision to secure the cover in this position. After use and removal, the cover 52 is again extended (see for example, Fig. 6). Accordingly, there is no disclosure in the Gross 1 reference of the displaceable cover 52 having any securing means coinciding with the first position such that the cover 52 is *secured* against the *bottom surface* of the device as recited by the Applicants.

Accordingly, for at least these reasons, the Applicants assert that the Gross 1 reference does not disclose or reasonably suggest each element as recited in independent claims 3 and 6, and respectfully request the withdrawal of the rejection under 35 U.S.C. 102(e).

Rejections of the Claims under 35 U.S.C. 103

The Examiner has also previously rejected claims 1 and 4 under 35 U.S.C. 103(a) as being unpatentable over Gross 1 in view of U.S. Patent No. 6,500,150 of Gross et al. (hereinafter Gross 2).

Specifically, the Examiner pointed to Gross 1 as disclosing a device for delivering a medicament having a housing with a top, a bottom surface adapted to contact a skin surface of a patient, a needle aperture on the bottom surface, and an injection needle adapted for penetration of the skin surface and for movement through the needle aperture.

The Examiner also pointed to Gross 1 as disclosing such a device further having a reservoir disposed within the housing in fluid communication with the injection needle, and a safety member adapted for movement away from the bottom surface and having a covering portion disposed about the needle aperture, and at least one shield protruding from the covering portion, the safety member having a first position wherein the shield of the safety member is initially disposed within the housing and the covering portion is substantially co-planar with the bottom surface of the housing, and a second position wherein the shield of the safety member is at least partially withdrawn from the housing and at least partially covers the needle.

The Examiner also pointed to Gross 1 as disclosing such a device further including a spring element configured to bias the shield and covering portion of the safety member toward the second position, and pointed to Gross 2 as disclosing such a device further including a movable door having a first position which prevents movement of the safety member, and a second position which allows movement of the safety member, such that the combination of the Gross 1 and Gross 2 references purportedly render obvious the device as recited by the Applicants in claims 1 and 4.

In regard to Gross 2, the Examiner pointed to the safety tab 27 as describing the movable door having a first position which prevents movement of the safety member, and a second position which allows movement of the safety member, as recited by the Applicants.

In regard to independent claim 1, the Applicants assert that the safety tab 27 of Gross 2 Figs. 2-4 is provided to prevent activation of the device, and not to prevent movement of any safety member. That is, the safety tab 27 is provided to prevent the housing 11 from rotating toward the base 11 (see col. 8, lines 14-25, and Fig. 5). Further, the safety tab 27 is rigid, and is slidably removed from the device for activation. In contrast, the Applicants recite an exemplary embodiment of the door to be rotatable as an example of the provided movement. As shown in Gross 2 Figs. 2-4, the safety tab 27 is pulled free of the device, and does not describe a door and more specifically, does not describe a rotatable door, as recited by the Applicants.

For these reasons, the Applicants assert that the Gross 1 and Gross 2 references separately or in combination, do not disclose or reasonably suggest each element as recited in claims 1 and 4, and respectfully request the withdrawal of the rejection under 35 U.S.C. 103(a).

Conclusion

In view of the above, it is believed that the application is in condition for allowance and notice to this effect is respectfully requested. Should the Examiner have any questions, the Examiner is invited to contact the undersigned attorney at the telephone number indicated below.

Respectfully submitted,

Ronald S. Grubb

Ronald S. Grubb
Reg. No. 48,672
Attorney for Applicants

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Roylance, Abrams, Berdo & Goodman, L.L.P.
1300 19th Street, N.W., Suite 600
Washington, D.C. 20036
T: (202) 659-9076